

Message Text

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PAGE 01 STATE 257402

21

ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-10 ISO-00 OES-05 MED-03 RSC-01

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DRAFTED BY: DHEW/FDA:JRWEINROTH, MD

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EUR/NSC-IG:JROUSE (INFO)

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----- 068358

R 212216Z NOV 74

FM SECSTATE WASHDC

TO AMEMBASSY SANTIAGO

AMEMBASSY BOGOTA

AMEMBASSY ATHENS

AMEMBASSY ROME

AMEMBASSY SEOUL

AMEMBASSY MEXICO

AMEMBASSY MADRID

AMEMBASSY TAIPEI

AMCONSUL HONG KONG

UNCLAS STATE 257402

E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, CI, CO, GR, HK, IT, KS, MX, SP, TW

SUBJECT: DEFECTIVE MEDICAL DEVICE - ANESTHESIA MACHINE.

1. FDA ADVISES THAT THE HEIDBRINK SERIES DM5000 CABINET KINET-O-METER ANESTHESIA MACHINES MANUFACTURED BY OHIO MEDICAL PRODUCTS, A DIVISION OF AIRCO, INC., MADISON, WISCONSIN 53701 BETWEEN 1968 AND AUGUST 31, 1971 (INCLUDES ALL SUCH DEVICES THAT HAVE MODEL NUMBERS 5000 THROUGH 5999) REQUIRE IMMEDIATE MODIFICATION.

2. PLASTIC SLIP-ON CAPS (FRICTION CAPS) ON NIPPLES IN THE
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PAGE 02 STATE 257402

OXYGEN PIPING SYSTEM ASSOCIATED WITH A BY-PASS VALVE HAVE,

ON A NUMBER OF OCCASIONS, BEEN DISLODGED, CAUSING OXYGEN TO FLOW INTO THE CABINET OF THE DEVICE, INSTEAD OF BEING DELIVERED TO THE PATIENT. IN THIS EVENT, UNLESS THE PATIENT'S CONDITION WAS BEING CONSTANTLY MONITORED, THERE IS THE LIKELIHOOD OF THE PATIENT SUSTAINING SEVERE HYPOXIA AND ENSUING BRAIN DAMAGE OR CARDIAC ARREST AND DEATH.

3. FOREIGN CONSIGNEES, AS FOLLOWS:

INDUSTRIA CHILENA DE SOLDADURAS S.A., CASTILLA 13850, SANTIAGO,
CHILE
TECNICA ELECTO-MEDICA, APARTADO AEREO 3752, (CARRERE 9A NO.
16-51 MEXANINE NO. 2), BOGOTA, COLOMBIA
DEM. A. GAVALOS, 2 GLADSTONE STREET, ATHENS, GREECE
THE VITA CO., P. O. BOX 1184, 40 -41 CONNAUGHT ROAD, W. (9TH FLOOR),
HONG KONG
CORALMA S.A.S., CORSO ANDREA, PODESTA 11-1, 16128 GENOA
ITALY
ASIA SCIENCE AND CO., I.P.O. BOX 1250, 24-23, 1-KA,
CHOONGMOO-RO, CHOONG-KU, SEOUL, KOREA
REPRESENTACIONES MEDICOTECHICAL S.A., MAZATLAN NO. 83,
MEXICO 11, D.F., MEXICO
PETROLEONS MEXICANOS, AVENIDA MARIA VACIONAL NO. 329, APTLOS
53-142 - 145, MEXICO 17, D.F., MEXICO
GUIDO RAYOS, ALVAREZ QUINTERO 2, MADRID 4, SPAIN
SHENG TUNG DEVELOPMENT CO., P. O. BOX 451, TAIPEI, TAIWAN,;
REPUBLIC OF CHINA

4. POSTS ARE REQUESTED TO ASCERTAIN WHETHER OR NOT THE CON-SIGNEES ARE FAMILIAR WITH THE FACT THAT THE MEDICAL DEVICE REQUIRES MODIFICATION FOR SAFE USE AND TO INFORM CONSIGNEES TO CONTACT OHIO MEDICAL PRODUCTS' REPRESENTATIVES SO THAT THEY MAY HAVE ANY DEFECTIVE MACHINES OF THIS MODEL SERIES MODIFIED AS PROMPTLY AS POSSIBLE. INGERSOLL

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To: SANTIAGO MULTIPLE
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